

Bureau of Indian Standards
Ghaziabad Branch Office

Date: 20 Sep 2024

Our Ref: GZBO/A-87002343

Subject: All India First Application for Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 4 cardiac defibrillators as per IS 13450 : Part 2 : Sec 4 : 2018

1. GZBO is in receipt of an application under Option 1 for grant of licence to use of BIS standard mark on the Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Sec 4 cardiac defibrillators as per IS 13450 : Part 2 : Sec 4 : 2018.

2. As per the information obtained from BIS Website/ Intranet, Circulars of CMD's to ROs / BOs, the following is observed:

- a) No BIS licence exists for the above-mentioned product.
- b) Marking fee not available for the product.
- c) Product Manual with SIT & Grouping guidelines available for the product.
- d) No test facility exists at any BIS laboratory or any BIS recognised laboratory.
- e) As per BIS intranet circular, one circular regarding application for grant of All India first licence is available for IS 13450 : Part 2 : Sec 4 : 2018.

3. In the view of above, the application may be considered as the All India First application for the certification of the above product.

4. All ROs and BOs are requested to send information regarding the above product by mail with respect to any application pending at their end or any other information which may be helpful to process this application.

5. CMD-III is requested to provide us with relevant latest guidelines, Marking Fee if any prevailing for the product.

6. All labs/LRMD are requested to confirm the availability of testing facilities & testing charges as per IS 13450 : Part 2 : Sec 4 : 2018.

HGZBO
DDGC

J. K. Singh
20/9/24



Naveen K
Sc 'D' / JD, GZBO

HCMD-III

HLRMD

All ROs/BOs

ITSD - For circulation on BIS Intranet